

Lloyd WOLFINBARGER
Appln. No. 08/646,519

agitating said second cleaned bone graft with a third solvent comprising one or more decontaminating agents to produce a third cleaned bone graft, wherein said third cleaned bone graft is essentially free from bone marrow.--

REMARKS

Claims 1-29, are pending in the present application. Claim 1 has been amended to require that sonication is carried out at a temperature of from 37° to 50° C. Support for this amendment is found at page 17 of the present specification, and in the examples. Claim 2, 5 and 13, have been canceled without prejudice or disclaimer. New claim 27 represents claims 1 and 9 written in independent form without the temperature range limitation. Claims 10-12 have been amended to be correct claim dependency. New claim 28 reflects claim 16 rewritten in independent form. New claim 29 reflects claim 17 written in independent form. No new matter has been added.

I. At page 2 of the Office Action, claim 7 has been objected to as being in improper form because a multiple dependent claim should refer to other claims in the alternative only.

The Examiner contends that claim 7 does not refer to claims 1, 2, 3 or 4, in the alternative. However, claim 7 recites "...as claimed in any one of claims 1, 2, 3 **or** 4." (emphasis added). Claim 7 as written does refer to the other claims in the alternative only. Accordingly the

Lloyd WOLFINBARGER
Appln. No. 08/646,519

Examiners objection is respectfully traversed. If the Examiner is to maintain this objection, clarification is requested.

II. At page 2 of the Office Action, claims 1-6 and 8-26 have been provisionally rejected under the judicially created doctrine of double patenting over claims 1-27 of copending Application No.: 08/546,529.

The Examiner states that the subject matter claimed in the instant application is fully disclosed in the cited copending application and would be covered by any patent granted on that copending application.

Applicant will file a terminal disclaimer in the appropriate case upon indication of allowable subject matter.

II At page 3 of the Office Action, claims 1,5-6 and 8-19 have been rejected under 35 U.S.C. sec. 102(b) as being anticipated by Elledge et.al.

The Examiner contends that Elledge discloses a method for producing a cleaned bone graft by sonicating the bone graft with detergents. The Examiner points to Elledge at col. 3, lines 45-60. A brief analysis of Elledge is set forth below.

Elledge is directed to a machine and process for cleaning tissue including bone, as well as equipment including electronic articles. Elledge discloses a two-step process, where in the first

Lloyd WOLFINBARGER
Appln. No. 08/646,519

step the article to be cleaned is subjected to a positive pressure stream of sterile water, and in the second step the article is sonicated in water optionally containing a surfactant.

Regarding the first cleaning step, at col. 7, Elledge discusses cleaning a bone segment by first sterilizing the system apparatus (col. 7, lines 24-25). This is accomplished by first flushing through a "first fluid" (101b) containing a "sterilant." Elledge discloses such sterilants at col.6 as substances such as "CYDEX" or "OMNICIDE." At col. 7, lines 33-35 Elledge discloses introducing deionized water "101b." The bone is then cleaned using a positive pressure stream of deionized water (col. 7, lines 31-33). At col. 5, lines 61-63, Elledge discloses that article "A" is cleaned using "high pressure fluid 135 (fluid 135 being second fluid 101c)..." Fluid 101c is deionized water (see col.6, lines48-49). Elledge does not teach or suggest cleaning bone using a positive pressure stream of a solution containing a detergent. Rather, Elledge requires in the first step of his process, cleaning with water *only*.

Elledge requires performing the first step using a positive pressure stream of water to clean bone. Thereafter, Elledge discloses performing a second cleaning step only if necessary. See Elledge at col.7, lines 49-50. Again, Elledge discloses first using a sterilant to clean the apparatus. At col. 7, lines 56-60, Elledge discloses cleaning the bone by submerging it in a second liquid mixture of deionized water and surfactant and sonicating to clean, followed by

Lloyd WOLFINBARGER
Appln. No. 08/646,519

rinsing and soaking. Elledge discloses that the process is carried out at a "working temperature range" which is defined at col.7, lines 12-13 as being in the range of from 27° to 33° C. In view of the following this rejection is respectfully traversed.

Regarding claim 1, claim 1 has been amended to require that the bone graft be sonicated at a temperature of from 37° to 50° C. Support for this amendment appears at page 17 of the present specification. Elledge does not teach or suggest carrying out the second step of his process at temperatures outside the disclosed range of 27° to 33° C.

Regarding claim 5, claim 5 has been canceled without prejudice or disclaimer.

Regarding claims 6 and 8, these claims are dependant upon claim 1. Claim 1 as amended requires sonicating at a temperature of from 37° to 50° C. Elledge does not teach or suggest the claimed temperature range.

Regarding claim 9, claim 9 requires *simultaneously* sonicating and subjecting the intact bone graft to a pressure mediated flow of solvent through an opening in the bone shaft. Elledge does not teach or suggest such simultaneous cleaning. Rather Elledge requires a two-step process with the

Lloyd WOLFINBARGER
Appln. No. 08/646,519

first step being cleaning using a positive pressure stream of water, and the second step being cleaning using sonication. Elledge does not teach or suggest using a positive pressure stream of solvent as required by present claim 9. Rather, Elledge discloses the use of deionized water only. Please see the above analysis of Elledge. Lastly, claim 9 is also dependent on claim one and claim one requires that the step of sonicating be carried out at a temperature of from 37° to 44 C. New independent claim 27 reflects claims 1 and 9, without the temperature range limitation.

Regarding claims 10-13, claim 13 has been canceled without prejudice or disclaimer. Claims 10-12 are all either directly or indirectly dependent upon claim 9 or new claim 27, and therefore not anticipated. Please see the above discussion regarding claim 9. Claims 10-12 have been amended to be directly or indirectly dependent upon either of claims 9 or 27.

Regarding claim 14, claim 14 is directed to a method for producing a bone graft using a negative pressure mediated flow of solvent, where the solvent includes one or more detergents, and simultaneous therewith sonicating the bone with a solvent. Elledge does not anticipate claim 14. Elledge does not teach or suggest using a negative pressure flow to clean bone. Elledge teaches using a *positive* pressure stream of *water* only. Elledge does not teach using a positive pressure stream of water with a detergent, let alone a negative pressure mediated flow with a

Lloyd WOLFINBARGER
Appln. No. 08/646,519

detergent as required by present claim 14. Elledge does not teach simultaneously cleaning using a negative pressure flow and sonication as required by present claim 14.

Regarding claim 15, claim 15 has been amended to require that sonication be carried out at a temperature of from 37° to 50° C. Elledge does not teach or suggest the presently claimed temperature range.

Regarding claim 16, claim 16 has been canceled without prejudice or disclaimer and rewritten in independent form as new claim 28. Elledge does not anticipate new claim 28 since Elledge does not teach after sonicating in a solvent, sonicating the bone segment in an antibiotic, antimycotic and/or an antiviral agent followed by a third sonication step in a third solvent containing one or more decontaminating agents.

Regarding claim 17, Elledge does not anticipate claim 17 since Elledge does not teach the claimed temperature range of from 37° to 50° C. Further, Elledge does not teach agitating the bone graft with a solvent as required by claim 17. New claim 29 reflects claim 17 written in independent form without the recitation of the temperature range. Elledge does not anticipate new claim 29 since Elledge does not teach agitation.

Lloyd WOLFINBARGER
Appln. No. 08/646,519

Regarding claims 18-19, claims 18 and 19 are dependent upon claim 17 and further define agitation. Elledge does not anticipate these claims since Elledge does not teach agitation.

In conclusion, It is submitted that Elledge does not teach each and every element of the claimed invention as required for anticipation under 35 U.S.C. sec. 102. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

IV At page 4 of the Office Action, claim 5 has been rejected under 35 U.S.C. sec. 102(e) as being anticipated by Morse et. Al. '626.

The Examiner contends that '626 discloses a method for removing bone marrow whereby a high pressure solvent is introduced into the bone that inactivates bacteria, fungi, virus, and parasites. The Examiner points to example 5 in support of her position. Claim 5 has been canceled without prejudice or disclaimer. Accordingly, this rejection is rendered moot.

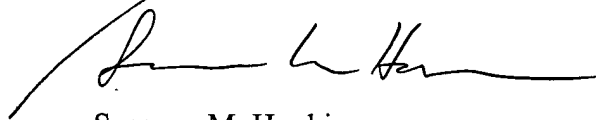
Lloyd WOLFINBARGER
Appln. No. 08/646,519

V. *It is noted that there are no art rejections of claims 20-26. Accordingly, the Examiner is requested to indicate these claims allowable if rewritten in independent form.*

In view of the above remarks and amendments, it is submitted that Elledge does not teach each and every element of the claimed invention as required for anticipation under 35 U.S.C. sec. 102. Accordingly, review, reconsideration and allowance of the present claims are respectfully requested. The Examiner is invited to contact the undersigned at her telephone number on any questions that may arise.

Respectfully submitted,

JONES & VOLENTINE, L.L.P.



Susanne M. Hopkins
Attorney for Applicants
Registration No. 33,247

Date: October 20, 1997

JONES & VOLENTINE
12200 Sunrise Valley Drive
Suite 150
Reston, Virginia 20191
(703)715-0870